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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,521	06/04/1999	MARK F. PITTENGER	640100-326	3211

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/22/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/319,521	PITTENGER ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13,36,39 and 69-99 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,5-13,36 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed 2-3-03 (Paper No. 17) is acknowledged and has been entered.

Claims 80-99 have been added. Claims 1-3, 5-13, 36, 39, and 60-99 are pending. Claims 1-3, 5-13, 36, and 39 have been withdrawn from consideration as being drawn to the non-elected invention.

Claims 60-99 are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

MAINTAINED Claims 60-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnstone et al. (US Patent #5,908,784), as evidenced by www.voigtglobal.com/Cellgro_basal_liquid.htm.

Response to Arguments

Applicant traverses the rejection on the grounds that Johnstone et al. does not disclose that the chondrogenic medium may include a simple sugar in an amount of from about 3 g/l to about 7 g/l and further notes that the only specific concentration of glucose disclosed by Johnstone et al. is 1 g/l. Applicant further contends that the Cellgro web page adds which discloses various formulation of DMEM one of which contains 1 g/l and another of which contains 4.5 g/l of glucose, adds nothing to the rejection.

However the examiner notes that as stated in the rejection of record, Johnstone et al. teaches that the mesenchymal stem cells are preferably isolated, expanded human mesenchymal stem cells cultured in a chemically defined serum free environment, and that the serum free media comprises a chemically defined minimal essential medium, ascorbate or an analog thereof, an iron source, insulin or an insulin like growth factor, in an Eagle's based media such as

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DMEM. Since the Cellgro web page teaches that DMEM typically contains with 1 to 4.5 g/L of glucose, and thus the DMEM medium taught by Johnstone et al encompasses the media recited in the instant claims. That Johnstone exemplifies a specific concentration of glucose such as 1 g/l, does not teach away from the broader teachings of Johnstone. The examiner also notes that the term "about" recited in the instant claims when referring to the glucose concentrations.

Applicant also traverses the rejection on the grounds that Johnstone et al does not disclose that TGF-beta3 may be used as a chondroinductive agent. However it is noted that the instant claims do not recite that TGF-beta3 may be used as a chondroinductive agent, and therefore said latter traversal is moot.

Therefore though applicant's arguments have been carefully considered, the rejection is maintained essentially for the reasons of record.

NEW GROUND OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 60-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnstone et al. (US Patent #5,908,784), in view of Hunziker (US Patent No. 5,368,858).

Johnstone et al teaches as above.

Johnstone et al does not teach the use of TGF- β 3.

Hunziker et al teaches the use of TGF- β 3 in a method of proliferating chondrocytes and states that the activity among members of the TGF- β family are similar (see entire patent including column 8, lines 7-24). Hunziker et al also teaches that mesenchymal cells when exposed to TGF- β 3 will be transformed into a chondrocytes (see entire patent, including column 5, lines 28-33 and 59-67, and claim 1). Hunziker et al also teaches that dosages of 2-10 ng/ml of TGF- β , see entire patent, especially column 18, claim 11).

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Therefore, one of skill who wanted to produce chondrocytes from mesenchymal stem cells and to induce chondrogenesis in mesenchymal stem cells, would have been motivated to have used the method taught by Johnstone et al as applied to claims 60-79 discussed supra, and to have substituted TGF- β 3 as recited in the claims 80-99, for the chondroinductive agent TGF- β 1 taught by Johnstone et al, because Hunziker teaches that the activity among members of the TGF- β family are similar, that TGF- β 3 can be used in a method of proliferating chondrocytes, and that mesenchymal cells when exposed to TGF- β 3 will be transformed into a chondrocytes. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

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Amy DeCloux, Ph.D.
Patent Examiner,
April 17, 2003

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A handwritten signature in black ink, appearing to read "Pat J. Nolan".

Patrick J. Nolan, Ph.D.
Primary Patent Examiner,
Group 1640